

## REMARKS

The Office Action mailed 19 November 2010, has been received and its contents carefully noted. Claims 1, 3-5, 21, 24, 25, and 36 were pending, claims 1, 3-5, 21, 24, 25, and 36 were rejected. By this amendment, claim 1 has been amended and claim 36 has been canceled without prejudice or disclaimer. Applicant has amended claim 1 to indicate that the isolated amino acid sequence comprises a fragment of SEQ ID NO:4, but is not SEQ ID NO:4. The amendment is fully supported by the specification as originally filed and does not introduce new matter. For example, by determining the diabetogenic epitope sequence defined by SEQ ID NO:1, Applicant has produced and described an isolated amino acid sequence which is a fragment of SEQ ID NO:4, that comprises the diabetogenic epitope defined by SEQ ID NO:1 and wherein the isolated amino acid sequence is not SEQ ID NO:4. Further support is found throughout the application as originally filed. No statutory new matter has been added. Therefore, reconsideration and entry of the claims as amended are respectfully requested.

### **Claim Rejections 35 U.S.C. 102(b) based on MacFarlane (2003, IDS)**

The Examiner rejected claims 1 and 4 under 35 U.S.C. 102(b) as being anticipated by MacFarlane (2003, IDS).

In response, Applicant has amended claim 1 to be directed to an isolated amino acid sequence comprising a fragment of SEQ ID NO:4 and further comprising a diabetogenic epitope defined by EEQLRELRRQ (SEQ ID NO:1), and wherein the isolated amino acid sequence is not SEQ ID NO:4. It is respectfully submitted that MacFarlane, does not teach or suggest an isolated amino acid sequence comprising a fragment of SEQ ID NO:4 which further comprises the diabetogenic epitope EEQLRELRRQ (SEQ ID NO:1) and wherein the isolated amino acid sequence is not SEQ ID NO:4.

MacFarlane discloses a clone termed WP5212 encoding a protein with 90% identity to *Triticum aestivum* (wheat) storage protein. MacFarlane does not teach or suggest an isolated fragment of the protein encoded by WP5212. Accordingly, by this very limitation, MacFarlane cannot anticipate the subject matter of the amended claims.

MacFarlane discloses mass spectroscopy analysis of wheat gluten proteins digested with trypsin. Trypsin is an enzyme with very well defined specificity, as it hydrolyzes only the peptide bonds in which the carbonyl group is contributed either by an Arg or Lys residue (see

Wikipedia using search term “Trypsin” or <http://en.wikipedia.org/wiki/Trypsin>). The diabetogenic epitope EEQLRELRRQ (SEQ ID NO:1) contains 3 arginine residues that serve as possible cleavage sites for trypsin. Thus, mass spectroscopy analysis using trypsin would not result in an isolated amino acid sequence comprising diabetogenic epitope EEQLRELRRQ (SEQ ID NO:1). Accordingly, by this very limitation, MacFarlane cannot anticipate the subject matter of the amended claims which require the isolated protein to comprise the diabetogenic epitope EEQLRELRRQ (SEQ ID NO:1).

As MacFarlane does not teach each and every limitation as claimed, the rejection under 35 U.S.C. 102(b) must be properly withdrawn.

**Rejections under 35 U.S.C. 103(a) based on MacFarlane, in view of U.S. Patent No. 6,803,221 and MacFarlane, in view of U.S. Patent No. 6,927,041**

The Examiner rejected claim 3 under 35 U.S.C. 103(a) as being unpatentable over MacFarlane, in view of U.S. Patent No. 6,803,221. Also, the Examiner rejected claims 4 and 5 as being unpatentable over MacFarlane, in view of US Patent No. 6,927,041.

In view of the claim amendments, remarks and arguments presented above with regard to the 35 U.S.C. 102(b) rejection, Applicants respectfully submit that the rejections under 35 U.S.C. 103(a) are moot. In particular, the documents cited by the Examiner do not, alone or in combination, teach or suggest the claimed invention.

Therefore, these rejections under 35 U.S.C. 103(a) should properly be withdrawn.

**Rejection under 35 U.S.C. 102(e) based on U.S. Patent No. 7,214,786**

The Examiner rejected claims 1, 3-5, and 36 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 7,214,786. Specifically, the Examiner alleges that SEQ ID NO:118,877 of the ‘786 patent is identical to SEQ ID NO:4 of the instant application and further that this sequence includes SEQ ID NO:1 of the instant application.

In response, Applicants have amended claim 1 to recite an isolated fragment of SEQ ID NO:4. The ‘786 patent does not teach or suggest isolated fragments of SEQ ID NO:118,877. Further, the ‘786 patent does not teach or suggest isolated fragments of SEQ ID NO:118,877 which comprise a diabetogenic epitope defined by SEQ ID NO:1. Finally, the ‘786 patent does not teach or suggest an isolated fragment of SEQ ID NO:118,877 which comprises the

diabetogenic epitope defined by SEQ ID NO:1, and which is not SEQ ID:118,877. Accordingly, U.S. 7,214,786 does not teach or suggest the subject matter as set forth in the instant claims.

Therefore, the rejection under 35 U.S.C. 102(e) should properly be withdrawn.

**Rejections under 35 U.S.C. 103(a) based on U.S. Patent No. 7,214,786 in view of U.S. Patent No. 4,281,061**

The Examiner rejected claims 21, 24 and 25 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 7,214,786 in view of U.S. Patent No. 4,281,061.

In view of the claim amendments, remarks and arguments presented above with regard to the 35 U.S.C. 102(e) rejection in view of US 7,214,786, Applicants submit that the cited documents, alone or in combination, do not teach or suggest the subject matter as claimed.

Therefore, this rejection under 35 U.S.C. 103(a) should properly be withdrawn.

**Request for Interview**

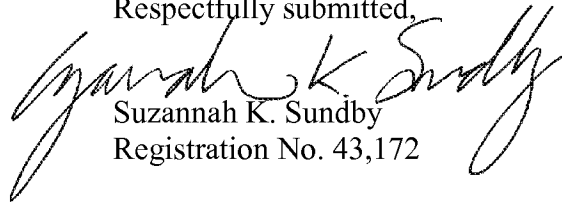
Either a telephonic or an in-person interview is respectfully requested should there be any remaining issues.

### CONCLUSION

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Therefore, it is respectfully requested that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Official action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. 1.136(a), and any fees required therefore are hereby authorized to be charged to **Deposit Account No. 024300**, Attorney Docket No. **034205.003**.

Respectfully submitted,



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